

“preventive treatment gel, not a toothpaste. Read directions carefully before using.”

(2) *For all stannous fluoride treatment rinse, preventive treatment gel, and dentifrice products.* “This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.”

(f) *Optional additional labeling statements—*(1) *For fluoride treatment rinses and preventive treatment gels.* The following labeling statement may appear in the required boxed area designated “APPROVED USES”: “The combined daily use of a fluoride preventive treatment” (select one of the following: “rinse” or “gel”) “and a fluoride toothpaste can help reduce the incidence of dental cavities.”

(2) *For dentifrice products containing 1,500 ppm theoretical total fluorine.* “Adults and children over 6 years of age may wish to use this extra-strength fluoride dentifrice if they reside in a nonfluoridated area or if they have a greater tendency to develop cavities.”

[60 FR 52507, Oct. 6, 1995; 60 FR 57927, Nov. 24, 1995; 61 FR 51187, Oct. 7, 1996]

EFFECTIVE DATE NOTES: The effective date of the regulation published at 60 FR 52508, Oct. 6, 1995, is delayed until Apr. 7, 1997. See 61 FR 52287, Oct. 7, 1996.

At 61 FR 52287, Oct. 7, 1996, §355.50 was amended by revising paragraphs (c)(1) and (c)(2), and in the headings for paragraphs (d)(1)(i) and (d)(1)(ii) by removing the word “Paste” and adding in its place the words “Gel or paste”, effective Apr. 7, 1997. For the convenience of the user, the superseded text is set forth as follows:

§ 355.50 Labeling of anticaries drug products.

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(c) * * *

(1) *For all fluoride dentifrice (toothpastes and tooth powders) products.* “Keep out of the reach of children under 6 years of age.” This warning shall be used in place of the first general warning statement required by §330.1(g) of this chapter.

(2) *For all fluoride rinse and gel products.* The first general warning statement in §330.1(g) of this chapter shall be used.

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§ 355.55 Principal display panel of all fluoride rinse drug products.

In addition to the statement of identity required in §355.50, the following statement shall be prominently placed on the principal display panel: “IMPORTANT: Read directions for proper use.”

§ 355.60 Professional labeling.

(a) The labeling for anticaries fluoride treatment rinses identified in §355.10(a)(3) and (c)(3) that are specially formulated so they may be swallowed (fluoride supplements) and are provided to health professionals (but not to the general public) may contain the following additional dosage information: Children 3 to under 14 years of age: As a supplement in areas where the water supply is nonfluoridated (less than 0.3 parts per million (ppm)), clean the teeth with a toothpaste and rinse with 5 milliliters (mL) of 0.02 percent or 10 mL of 0.01 percent fluoride ion rinse daily, then swallow. When the water supply contains 0.3 to 0.7 ppm fluoride ion, reduce the dose to 2.5 mL of 0.02 percent or 5 mL of 0.01 percent fluoride ion rinse daily.

(b) The labeling for products marketed to health to health professionals in package sizes larger than those specified in §355.20 shall include the statements: “For Professional Office Use Only” and “This product is not intended for home or unsupervised consumer use.”

Subpart D—Testing Procedures

§ 355.70 Testing procedures for fluoride dentifrice drug products.

(a) A fluoride dentifrice drug product shall meet the biological test requirements for animal caries reduction and one of the following tests: Enamel solubility reduction or fluoride enamel uptake. The testing procedures for these biological tests are labeled *Biological Testing Procedures for Fluoride Dentifrices*; these testing procedures are on file under Docket No. 80N-0042 in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and are available on request to that office.